Integrating Near-Field Sources and Pathways into Overall Exposure Modeling of Chemicals in Consumer Products

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significantly reduced exposure to organic aromatic contaminants (*cyp1a*), loss of metals exposure (*mt2*), and a loss of both morphometric and molecular cardiotoxicity. The persistent, low-level induction of *cyp1a* was not a result of inducers leaching from the bioretention materials, but instead suggests a small amount of organic contaminants make their way through the treatment.

24 Assessment of Chemical and Pathogen Risks at an Urban River

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Risk-based cleanups at contaminated urban river sites are typically driven by chemical stressors under regulatory programs, such as CERCLA. However, non-chemical stressors, including pathogens, are often equally problematic in urban waterways subject to point sources, such as combined sewer overflows (CSOs). Because of multi-stressor impacts, remedies focused on one system stressor (e.g., chemicals in sediment) without understanding the impacts and interrelationships of other system stressors runs the risk of recontamination and/or failure to achieve long-term objectives. In this paper, the risks to human health posed by potential exposures to chemical and pathogen stressors in an industrial urban river are evaluated. Using standard risk assessment tools and methods established in USEPA guidance, the risks to recreational users of the Lower Passaic River in New Jersey from exposures to chemicals and pathogens in the river are evaluated. Key elements of the problem formulation step, including the questions to be addressed, available data, and the risk assessment conceptual site model, are presented. The similarities and differences in the types of stressors, dose-response data, exposure and risk calculation methods, and the quantification and interpretation of the risk results are discussed, along with key uncertainties. While chemical risks are primarily associated with indirect exposure (i.e., fish consumption), pathogens pose significant direct contact risks. The findings of the dual risk assessments provide useful perspective on public health risks to recreational users of the Lower Passaic River and underscore the need for integrated approaches to cleanup at urban river sites.

Human Exposures to Chemicals in Consumer Products

25 Assessing User Exposure to Consumer Products: Methods Specific to Product Use and Exposure Route to Assess Consumer Health Risks

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Consumer Products Safety Commission, California's Proposition 65 regulations, as well as legal suits against manufacturers, have necessitated the development of exposure assessment methods to comprehensively address exposure to consumer products; this includes issues specific to classes of products and their uses. Although regulations on consumer products have been in place for decades, a variety of products have no standardized exposure assessment procedures. This presentation provides an overview of the contexts in which exposure assessments of consumer products are useful, methods that are currently being used to assess consumer exposures to the variety of everyday products, and a discussion of data gaps and uncertainties. Exposures to chemicals released from consumer products occur via ingestion, inhalation, and dermal contact. Examples of exposure routes commonly evaluated include direct ingestion of contaminant chemicals in packaged foods and dietary supplements, incidental ingestion of chemicals transferred from product via hand to mouth contact, inhalation of volatile chemicals released from products, dermal uptake of chemicals directly transferred to skin from handled products, absorbed from topically-applied products, or leached from electronic wearable devices into sweat and water on the skin as. Many types of consumer products may pose exposures via multiple pathways. To estimate chemical release and subsequent exposures from consumer products under typical use conditions, an understanding of the scenarios of product use including the frequency and duration of contact is required. Simulations using the product as intended, and sampling of chemicals transferred from the product, are essential tools in gathering representative data to support exposure estimation, particularly when no or few relevant data are available in the published literature. When data are available in the literature, statistical models of uptake may be developed to support exposure estimation. Data on the frequency and duration of product use are often difficult to ascertain from scientific literature and therefore must be gathered from the product manufacturer, surveys on product use, or based on generalizing observations of typical product use. Examples of assessment methods used for each of the plausible routes of consumer exposure are discussed.

26 California's Safer Consumer Products Program's Approach to Chemical Exposure Assessment

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The California Dept of Toxic Substances Control's Safer Consumer Products (SCP) Program is tasked with regulating products containing a Chemical of Concern and requiring product manufacturers to conduct an Alternatives Analysis. This novel regulatory program utilizes a narrative, rather than a prescriptive standard, to prioritize product-chemical combinations, giving DTSC the flexibility to evolve with emerging science. As a part of the process of prioritizing product-chemical combinations, the SCP Program must assess the potential for public and/or aquatic, avian, or terrestrial animal or plant organism exposure to the chemical in the product as well as evaluate if one or more of these exposures contributes to or causes significant or widespread adverse impacts. This presentation will detail the multiple factors that SCP may consider in assessing the potential for exposure to a chemical in a product, including exposure-related hazards, and the potential for that exposure to contribute to significant or widespread adverse impacts. An example of the use of this exposure assessment approach will be provided using one of the SCP program's recently named product-chemical combinations. This presentation will also identify data gaps that SCP has identified related to assessing exposure in consumer products.

27 Integrating Near-Field Sources and Pathways into Overall Exposure Modeling of Chemicals in Consumer Products

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Humans can be exposed to chemicals in consumer products during product use and environmental releases with inhalation, ingestion, and dermal uptake as typical exposure routes. Nevertheless, chemical exposure modeling has traditionally focused on the far-field with near-field indoor models only recently gaining attention. Further, models that are mostly emissions-based, may not necessarily be applicable to all types of chemical release from consumer products. To address this gap, we (1) define a framework to simultaneously account for exposure to chemicals in the near- and far-field, (2) determine chemical product concentrations for various functional use categories, (3) introduce a quantitative metric linking exposure to chemical mass in products, the Product Intake Fraction (PiF), and (4) demonstrate our framework for various consumer product categories. This framework lends itself to high-throughput calculations for characterizing exposure to the vast consumer product chemical space. The chemical mass in products is used as a starting point for quantifying human exposure obtained by multiplying the chemical concentration (e.g., % w/w) in the product with the amount of product used per defined application. Chemical concentrations in products can be obtained from empirical studies, formulations and associations described in databases, or when unavailable, estimated based on chemical-product functions or regulatory frame formulations. Exposure is quantified by estimating the PiF, the fraction of the chemical in a product that is

taken in by humans via each exposure route, considering specific points of entry into the near-field environment (releases of chemicals encapsulated in articles, indoor air spray, etc.). To estimate PiFs, we combined far-field environmental compartments with near-field points of entry and exposure pathways in a multi-media matrix of transfer fractions, with columns and rows for each compartment, point of entry, and exposure pathway. The multiple transfers and PiFs (e.g., from chemicals encapsulated in articles to inhalation of indoor air and dermal uptake via skin contact) were obtained by inverting the transfer fraction matrix, yielding steady-state multi-media transfer fractions. PiFs for various chemicals in products were found to be on the order of 1x10-7 for semi-volatile organic compounds (SVOCs) in thick flooring, 5x10-3 for VOCs in indoor air spray, and up to 95% or even higher for ingredients in leave-on cosmetic products.

28 Chlorinated Volatile Organics in Indoor Air from Consumer Products

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Many consumer products contain volatile organic compounds (VOCs) that are also the focus of soil and groundwater cleanups. The emissions of these VOCs from consumer products into indoor environments can result in air concentrations that are high enough to confound vapor intrusion (VI) investigations and exceed screening risk levels. In this study, emission rates of 1,2-dichloroethane, trichloroethene, tetrachloroethene, and carbon tetrachloride from consumer products were measured under laboratory conditions using a flow through system. The measured emissions were then used with a standard box model to estimate the indoor air concentrations that would be found if these products were introduced into a residence. To evaluate the suitability of this approach, the estimated concentrations were then compared to concentrations measured during several object release studies conducted in an actual residence. The estimated and measured concentrations were found to be within a factor of two, suggesting this approach can be useful for determining the relative impact of internal versus external VOC sources and for screening level risk evaluations.

29 Deterministic Exposure Assessment of Ingredients Used in Consumer Cleaning Products in the United States

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The American Cleaning Institute (ACI) has undertaken a transparency initiative that includes conducting screening-level risk assessment for ingredients used in consumer dish care, laundry care, and hard surface cleaning products in the United States. Following development of the ingredient inventory and compilation of the hazard database, our research group characterized exposure for approximately 680 identified ingredients resulting from the intended uses for each specific cleaning product. A major project milestone was development of the formulation database. Data on concentration for each ingredient was assembled from manufacturer product sheets, HPV chemical submissions, trade literature, government reports, and scientific publications. Primary data was not available for all ingredients, so extrapolation approaches were required. A functional use class was assigned to each ingredient to indicate its specific purpose within the product. Functional use classes from USEPA's Design for the Environment were used as a starting point, and additional classes were identified as necessary. In the absence of data, ranges of concentrations were applied to ingredients based on their functional use class within each product, and also using data for chemicals within a chemical category. Exposure scenarios considered oral, dermal, and inhalation exposures for adult women and children based on the known habits and practices for each product type. Direct and indirect exposures for each ingredient in each product type were then estimated using deterministic exposure equations. Aggregate exposures (for ingredients present in multiple product types) were also examined. For most ingredients, exposure was estimated on the order of hundreds of ng/kg/day to tens of ug/kg/day. These estimates of exposure will be used to calculate margins of safety in the next project phase. There are opportunities for refinement of these estimates, including further investigation of product ingredient concentrations and probabilistic approaches examining diversity in habits and practices.

30 Human Health Risk Assessment of Chloroxylenol in Liquid Hand Soap and Dishwashing Soap Used by Consumers and Health-Care Professionals

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A human safety assessment of chloroxylenol was conducted based on its use by consumers and health-care workers in liquid hand and dishwashing soaps. The assessment was initiated in response to the U.S. Food and Drug Administration's (FDA's) December 2013 Proposed Rule identifying data requirements for chloroxylenol and other Over-the-Counter (OTC) consumer antiseptic ingredients to obtain "generally recognized as safe and effective" (GRAS/GRAE) status (Fed. Reg. 2013, pp. 76444-76478). Toxicity data for chloroxylenol were summarized and the lowest no observed effect levels (NOAELs) were identified. While limitations exist in the toxicological database for chloroxylenol, substantial data indicate lack of genotoxicity, no evidence of carcinogenicity, and low systemic toxicity. Data from Momma et al. (1988) and Noda et al (1983), as well as Siglin et al. (1991), were used in this assessment to develop NOAELs for chronic toxicity including carcinogenicity and DART, respectively. Procedures described by Sanderson et al. (2006) were applied to estimate exposure to chloroxylenol resulting from three exposure pathways from use of two types of liquid products including two pathways related to dishwashing products, and one related to antimicrobial hand soap. In each case, "high exposure" and "low exposure" scenarios based on the expected use patterns and daily exposure levels, are considered. Different age groups are considered where appropriate. Identified NOAELs were used together with exposure estimates to derive margin of exposure (MOE) estimates for chloroxylenol resulting from this use. Many aspects of these estimates were likely to overestimate exposure and risk (i.e., high assumed contact frequency, selection of lowest available NOAELs addressing sensitive receptors and endpoints). The resulting MOEs ranged from 165 to over 100,000,000. While there are some limitations in the toxicological data for chloroxylenol, the finding that all MOEs were greater than 150 despite the use of many health protective assumptions indicates negligibly small potential for harm related to consumer or health-care worker exposure to chloroxylenol in liquid soaps used in dishwashing and hand washing. Moreover, given the large MOEs based on the current sizable toxicity data base, it seems unlikely that additional studies would alter conclusions about safety.

31 Asthma Hazard Characterization and Exposure Assessment Approaches for Evaluation of Consumer Product Ingredients

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Asthma is a complex syndrome with significant consequences for those affected. The number of individuals affected is growing, although the reasons for the increase are uncertain. Concerns have been raised regarding the potential for consumer products, including cleaning products, to cause or exacerbate asthma or asthma-like responses. Current risk assessment methods cannot adequately assess the potential for consumer product ingredients to trigger asthma or asthma-like responses; epidemiological studies can only measure possible effects associated with a multitude of chemicals and products, and no single animal model can reliably replicate the complexity of an asthma-like response in humans. To characterize asthma and respiratory related hazards associated with consumer products, a decision system was developed that included sequential data analysis techniques. A hazard characterization process employing a weight of evidence basis for assessing the current human effects literature was used to identify current gaps in our understanding of asthma and relationships with cleaning product use. The resulting